

Serial. No. 09/911,051

REMARKS

Status of the Claims

Claims 1-17, 19, 21-29 and 31-36 remain pending. The claims are presented above for the Examiner's convenience.

Objection to the Drawings

The drawings are objected to under 37 CFR 1.83(a). According to the Office Action, the drawings must show every feature of the invention specified in the claims. Although Applicant respectfully disagrees, new Fig. 3 has been added and the specification amended to avoid delay in the prosecution in the present application. Support for new Fig. 3 and the changes to the specification can be found, for example, in original claim 13, in Fig. 2 and the associated discussion in paragraph [0023], as well as in paragraphs [0010] and [0035]. No new matter is added.

Reconsideration and withdrawal of the objection to the drawings is requested.

Rejection of claims 1, 13 and 31-33 under 35 U.S.C. §102(e)

Claims 1, 13 and 31-33 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,316,018 (Ding). The reference is the U.S. counterpart to EP 0 879 595 A2, which was distinguished in applicant's response to the Office Action of August 12, 2003 in the present application. This rejection and its supporting remarks are respectfully traversed.

"To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim." *Brown v. 3M*, 265 F.3d 1349, 60 USPQ2d 1375 (Fed. Cir. 2001). However, claim 13, and claims 1 and 31-33 depending therefrom, are directed to a medical device for long-term implantation that comprises, *inter alia*, a reservoir that is adapted for long-term release of an antimicrobial agent. As defined in paragraph [0024] of the present specification, long term release is release over a period of at least three months.

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Such a device is not described in Ding, which instead describes a device that provides release on the order of several days. See, e.g., Fig. 1 of Ding, in which release is measured out to 8 days, and Table 6a, which sets forth release data at 11 days.

Hence, claims 1, 13 and 31-33 are novel over Ding for at least this reason.

Nor are claims 1, 13 and 31-33 obvious over Ding under the provisions of 35 U.S.C. §103(a).

For example, each of claims 1, 13 and 31-33 is directed to a medical device having a reservoir that comprises an antimicrobial agent disposed within a polymer matrix, which reservoir is adapted to release the antimicrobial agent from the polymer matrix over a period of at least three months. A surfactant region is disposed over the reservoir at an outer surface of the medical device, and a barrier layer is disposed between the polymer matrix and the surfactant region.

As seen from Fig. 1 and its accompanying discussion in paragraph [0022] of the present specification, it is believed that the surfactant and antimicrobial agent of the present invention work more or less in series, with the surfactant initially providing the bulk of the anti-bacterial effect by resisting adherence of living bacteria (as well as dead bacteria and host protein). Unfortunately, due to degradation of the surfactant, the efficacy associated with the surfactant-modified surface decreases over time. The antimicrobial agent, however, eventually reaches the surface of the medical device to make up for the surfactant's loss in efficacy, preventing living bacteria from actively colonizing the medical device. Due to the long-term release characteristics of the reservoir that contains the antimicrobial agent, the antimicrobial effect is a sustained one.

In contrast with the present invention, the surfactant and the drug in the Ding reference work in tandem with one another. Specifically, an ionically charged surfactant is used in Ding to delay release of an oppositely charged drug. See, for example, page 3, lines 51-54 of Ding:

In accordance with the present invention, negatively charged drugs contact positively charged surfactants to form a complex. Once the complex is formed, the solubility of the drug in body fluid is significantly reduced. Thus, the release rate of the drug in the body fluid is decreased. Similarly, positively charged drugs can form complexes with negatively charged surfactants to achieve similar results.

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Hence, in contrast to the presently claimed invention, Ding teaches those of ordinary skill in the art to delay release through the use of an ionic-surfactant-containing layer, rather than through varying the release characteristics of the polymeric reservoir layer that is disclosed therein.

In view of the above, reconsideration and withdrawal of the rejection of claims 1, 13 and 31-33 as being unpatentable over Ding are respectfully requested.

Allowable Subject Matter

Applicant notes with appreciation the indication of allowable subject matter in claims 2-12, 14-29 and 34-36. (Although it is noted that claims 18 and 20 were previously deleted in Applicant's response to the Office Action of March 13, 2003, which was filed on June 13, 2003.)

CONCLUSION

Applicants submit all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, the Examiner is requested to telephone the Applicant's attorney at (703) 433-0510 in order to resolve any outstanding issues in this case.

FEES

The Office is authorized to charge the additional claims fee as well as any other fees required to deposit account number 50-1047.

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Respectfully submitted,



David B. Bonham
Registration No. 34,297

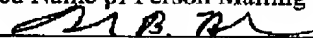
Attorney for Applicant
Mayer Fortkort & Williams, PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
Tel.: 703-433-0510
Fax: 703-433-2362

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